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| 10/081,641 | 02/22/2002 | Patrick A. Haverkost | 01-199US01 [209.0120001] | 2371 |
| 54953 7590 12/24/2009 BROOKS, CAMERON & HUEBSCH, PLLC 1221 NICOLLET AVENUE SUITE 500 MINNEAPOLIS, MN 55403 | | | EXAMINER LANG, AMY T | |
| | | | ART UNIT 3731 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/081,641 | Applicant(s) HAVERKOST ET AL. | |
| | Examiner AMY T. LANG | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-29,31-33,47,48,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) 9,12-16,18-29,48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10,11,17,31-33,47 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/28/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 3-8** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 3-8 recite wherein the anchoring means is a balloon. However, claim 1, from which claims 3-8 are dependent, teach the anchoring means as anchoring only the proximal end of the stent while the distal end of the stent is unsheathed. Therefore, since only the distal end is unsheathed, the proximal end must still be constrained by the retrograde. It then follows that the stent is anchored within the sheath. However, the instant specification teaches the balloon as compressing the expanded stent against a lumen wall and not constraining it within a sheath (see page 9 lines 8-30 of the instant specification).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 3-8** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claim 3-8 recite wherein the anchoring means is a balloon. However, claim 1, from which claims 3-8 are dependent, teach the anchoring means as anchoring only the proximal end of the stent while the distal end of the stent is unsheathed. Therefore, since only the distal end is unsheathed, the proximal end must still be constrained by the retrograde. It then follows that the stent is anchored within the sheath. It is then unclear as to how a balloon can anchor and constrain a stent within an outer sheath.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 10, and 11** are rejected under 35 U.S.C. 102(b) as being anticipated by Euteneuer et al. (US 5,989,280).

With regard to **claim 1**, Euteneuer et al. (hereinafter Euteneuer) discloses an introducer for deployment of an endoluminal device in a body lumen (see entire document). As shown in Figure 1, the device comprises a shaft (50) and an inner sheath (12) mounted concentrically over the shaft. Stent (17) is then mounted concentrically over the shaft (Figure 1). Sleeve (14) is mounted over a distal portion of the stent so that distal movement of the sleeve unsheathes the distal portion of the stent (column 6, line 66 through column 7, line 10). Therefore sleeve (14) clearly overlaps

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the claimed anterograde sheath. Furthermore, this anterograde sheath of Euteneuer is indirectly attached to the proximal tip of the shaft (50).

Sleeve (16) therefore overlaps the claimed retrograde sheath since it is mounted over a proximal portion of the stent such that proximal movement of the sleeve unsheathes the proximal portion of the stent (column 6, line 66 through column 7, line 10). As shown in Figure 3, when the retrograde sheath is fully retracted the retrograde sheath and the anterograde sheath are laterally spaced from one another.

Euteneuer fully teaches bands (18 or 60) that anchor the stent to the inner sheath (column 7, line 22-50). The bands are constructed so that they dissolve in water when exposed within the patient. Therefore, when the anterograde sheath has been moved distally to expose the distal portion of the stent, then only the bands on this distal end are exposed and will dissolve. This causes only the distal portion of the stent to expand since the proximal portion is still secured under the retrograde sheath and by proximal bands that have not yet dissolved. Euteneuer teaches this embodiment where the distal end of the stent is released first (column 7, lines 41-46). Therefore, the anchoring means of Euteneuer are configured to engage and anchor only a proximal portion of the stent while the distal portion has been unsheathed. The bands also minimize axial movement of the stent since it holds the stent in place against the inner sheath.

With regard to **claim 10**, L-seal (25) provides sufficient space between the inner sheath and the anterograde sheath to contain the stent and therefore overlaps the claimed radial spacer.

With regard to **claim 11**, the radial spacer of Euteneuer is indirectly attached to the distal tip.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 31-33, 47, and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Euteneuer (US 5,989,280).

With regard to **claim 31**, Euteneuer discloses the invention substantially as claimed wherein a stent is constrained by an anterograde and a retrograde sheath. However, Euteneuer does not specifically teach wherein the anterograde sheath extends a greater length over the stent than the retrograde portion. However, such would have been obvious at the time of the invention and involve a mere change in size. Additionally, the instant disclosure describes this parameter as merely preferable and

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does not describe it as contributing any unexpected result to the device. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

With regard to **claim 32**, when only the anterograde sheath has moved proximally, the anterograde sheath and retrograde sheath are laterally spaced and the retrograde sheath has not moved.

With regard to **claims 33 and 51**, the anterograde sheath and retrograde sheath of Euteneuer laterally overlap and abut one another before either sheath has moved (Figure 1).

With regard to **claim 47**, Euteneuer teaches that the stent may also comprise a balloon expandable stent so that a balloon would be placed between the inner sheath and stent (column 5, lines 62-63). Although Euteneuer does not specifically teach the balloon as only under the retrograde sheath or anterograde, such would have been obvious at the time of the invention to allow for only a portion of the stent to expand.

10. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Euteneuer (US 5,989,280) in view of Zadno-Azizi et al. (US 6,022,336).

Euteneuer discloses the invention substantially as claimed wherein a stent is constrained by an anterograde and a retrograde sheath. However, Euteneuer does not disclose a medial sheath located between the inner sheath and the retrograde sheath.

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Zadno-Azizi et al. (hereinafter Zadno-Azizi) teaches that a reinforcing layer, specifically a metal braid, is well known in the art to provide increased stiffness (column 9, lines 51-59). It is the examiner's position that such a reinforcing layer overlaps the instantly claimed sheath. It is further the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention for the introducer of Euteneuer to comprise an additional layer of a braided metal sheath between the inner sheath and retrograde sheath to provide increased stiffness.

Since Zadno-Azizi further teaches the advantage of providing variable stiffness along the length of an introducer (column 9, lines 51-54). Variable stiffness allows the introducer be sufficiently rigid to travel through a patient's vasculature but still flexible enough to allow for quick turns through torturous anatomy. The variable Zadno-Azizi is accomplished by providing the proximal region with greater stiffness than the distal region. Therefore, it would have been obvious to one of ordinary skill in the art for the reinforcing braided sheath to terminate proximal the distal end portion of the introducer. This would produce a braided sheath that terminates proximal of the balloon.

Response to Arguments

11. Applicant's arguments with respect to claims 1, 3-8, 10, 11, 17, 31-33, 47, and 51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/18/2009

/Amy T Lang/

Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/

Supervisory Patent Examiner, Art Unit 3731

12/18/09